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10/816,636	04/01/2004	Patrick T. Petruno	10040213-1	1047
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Kathy Manke Avago Technologies Limited 4380 Ziegler Road Fort Collins, CO 80525			EXAMINER YU, MELANIE J	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 07/24/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/816,636

Applicant(s)

PETRUNO ET AL.

Examiner

MELANIE YU

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 21-23, 26 and 39-41 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11, 12, 21-23, 26 and 39-41 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 April 2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 11, 12, 21-23, 26 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2002/0004246) in view of Crosby (US 6,217,744) further in view of Holmes, II et al. (US 5,371,687).

Daniels et al. teach a test system comprising: a medium containing a labeling substance that comprises first persistent fluorescent structures that emits light having a first frequency and second persistent fluorescent structures that emit light having a second frequency, wherein each of the first persistent fluorescent structures is attached to a substance that is capable of binding the first structure to a target analyte when a sample containing the target analyte is applied to the medium (each detection reagent is associated with a nanocrystal having a distinct emission peak and nanocrystal is a persistent fluorescent structure, par. 207; capture and control reagents bind the first and second structures and are present in a chromatographic medium therefore the first and second nanocrystal structures are present in a medium, par. 201; emission peak of nanocrystal incorporated into control is distinct from that exhibited by nanocrystals of the first detection reagent therefore first and second nanocrystals emit at different frequencies, par. 198); a light source positioned to illuminate a target area and a control area on the medium (par. 213); a first photodetector positioned to measure light of the first frequency originating from the target area of the medium (multiple detectors for each light emission frequency, par. 214); and a second photodetector positioned to measure light of the second frequency originating from the control area, wherein a signal from the second photodetector indicating an intensity above a threshold level indicates that the sample has passed through the target area (separate detector for each detection region with a different emission frequency, par. 214; control region has a different emission frequency than detection region, par. 198; detection of nanocrystals in the control region occurs in the presence or absence of analyte and therefore

indicates that the sample has passed through the medium, par. 242). Daniels et al. fail to teach the first and second photodetectors and medium contained in a single-use module that can be inserted into a reusable module and the single use module comprising an external terminal receiving electrical power for the light source, the first and second photodetectors and communicating signals between the reusable module and the single use module and a terminal located on an external surface of the single use module for conductively receiving electrical power.

Crosby teaches a photodetector and medium necessary for optical detection contained in a single use module (optical components and porous membrane are part of the disposable device, optical components comprise the photodetector, col. 5, lines 64-col. 6, line 13) and inserted into a reusable module for communication of test signals between the single-use module and reusable module (communication between disposable analysis device and information gather and storage system, disposable device is single use and information gathering system is reusable, col. 6, lines 57-67; col. 7, lines 37-45) and the single use module comprising an external terminal receiving electrical power for the electronics in the device, including light sources and photodetectors (capacitor is external terminal that receives electrical power, col. 8, lines 28-40; electronics include light source and photodetectors, col. 6, lines 46-50), wherein the reusable module has a receptacle into which the external terminal of the single use module can be inserted to provide electrical power and communicates test signals between single use module and reusable module (device is brought in proximity to console, col. 8, lines 28-40; device may alternatively be placed into the console for

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transfer of data and to provide electrical power, col. 7, lines 6-10), in order to provide a self powered device that resists corrosion and degradation. Crosby teaches that while not preferable, it is possible to directly electrically connect the device to a reader for power supply and information gathering (col. 6, lines 57-67) and Crosby also teaches that power to the diagnostic device may be provided inductively, but not conductively, by an electrical power source external to the single-use module (col. 8, lines 28-40). All disclosures of non-preferred embodiments must be considered. *In re Nehrenberg*, 126 PQ 383. *In re Boe*, 148 PQ 507. *In re Mill and Palmer*, 176 PQ 196 (CCPA 1972). *In re Simon*, 174 PQ 114. *In re Lamberti et al.*, 192 PQ 278 (CCPA 1976).

Holmes, II et al. teach a module that has a terminal for insertion of a single use module (housing mated to data processing module, col. 3, lines 6-10), that has a terminal located on an external surface of the single-use module for conductively receiving electrical power from a source external to the single-use module (housing is mated to data processing module and conductors connect the module to an external power supply, col. 3, lines 19-36), in order to provide glucose measurements in a device that can interface with a printer, store larger numbers of patient glucose numbers, perform various calculations and interface a number of different types of glucose measurements to a computer.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the test system of Daniels et al., the photodetectors and medium necessary for optical detection contained in a single use module that can be inserted into a reusable module for communication of test signals as

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taught by Crosby, in order to provide small, point of care diagnostic tests that are small in size and produces a fast quantitative or qualitative result with increased reliability. Although Crosby does not specifically teach two photodetectors, it would have been obvious to include all photodetectors of Daniels et al. necessary for detection in the single use device taught by Crosby. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Daniels et al. in view of Crosby, a terminal located on an external surface of the single-use module for conductively receiving electrical power from a source as taught by Holmes, II et al., in order to provide sample measurements over an extended period of time longer than the battery life of a device. Although Holmes, II et al. do not specifically teach the module having a terminal being single use, such a limitation is drawn to intended use of the module and claim 11 does not recite any specific structural limitations that render the module single-use. Since the module of Holmes, II et al. teach the structural limitations for a single use module as recited in claim 11, which is the module having a terminal on the external surface of a module which can be inserted into a reusable receptacle for providing electrical power and communicating test signals, and the module of can be removed from the reusable module, the module having a terminal as taught by Holmes, II et al. is capable of being disposed after a single use.

With respect to claims 12 and 21, Crosby teaches the reusable module implementing a user interface capable of indicating a test result on a display (console is the information gathering and storage system and has a display screen to display results from the disposable device, col. 7, lines 37-50).

Regarding claim 22, Crosby teaches that the test signals are electrical signals (col. 7, lines 14-25).

With respect to claim 23, Daniels et al. teach the first and second persistent fluorescent structures comprising quantum dots (par. 198 and 79).

Regarding claim 26, Daniels et al. teach the medium comprising a lateral-flow strip for performing a binding assay (par. 200-201) and the target area containing an immobilized substance that binds to and holds the complex including one of the first persistent structures and the target analyte (par. 200-201; capture reagent binds to the detection complex, par. 189; detection complex comprises analyte and nanocrystal, par. 137-139; capture reagent is in a capture region, par. 115).

With respect to claims 39 and 40, Daniels et al. teach the second persistent structures bind to the control strip (control ligands are in a control region, par. 115; control ligands bind to second persistent structures that have an emission frequency different from that in the capture region, par. 198). Daniels et al. also teach a first and second color filter corresponding to the first and second photodetector that transmit the first and second frequencies, respectively (multiple detectors are present, one for each region, and each has a bandpass filter for detecting a narrow wavelength range corresponding to the nanocrystal emission wavelength in the capture and control regions, par. 214).

With respect to claim 41, Daniels et al. teach the control area containing an immobilized substance that binds and retains the labeling substance (par. 26 and 38).

Response to Arguments

3. In response to applicant's amendment filed on 28 April 2008, rejections under 35 USC 112, first paragraph have been withdrawn.
4. Applicant's arguments filed 28 April 2008 regarding the rejections under 35 USC 103(a) have been fully considered but they are not persuasive. At page 7, applicant argues that the reusable module of Crosby et al. is not "inserted" into the reusable module and is instead placed upon an indentation on the external surface of the reusable module. Applicant's argument is not persuasive because Crosby is not relied upon for the limitation of the terminal of the single use module to be inserted into the reusable module. Holmes is relied upon for this limitation.
5. At page 8, applicant argues that it is clear that the instrument disclosed by Holmes is a multiple use glucose measuring instrument and therefore Holmes does not disclose, teach or suggest a single-use module of any kind. Applicant's argument is not persuasive because although the measurement module of Holmes may be used multiple times, such a limitation is drawn to intended use of the product and the product of the prior art must only be capable of being used as a single use device. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Claim 11 does not recite any specific structural limitations that make the module single-use. Holmes teaches the required limitations for a single use module as described above, and can be removed from the reusable

module. Therefore the module having a terminal, as taught by Holmes, is capable of being disposed after a single use.

6. At page 9, applicant argues that it is clear that Crosby suggests not using a direct electrical connection, which teaches away from the claimed invention and it would not be obvious to use a direct electrical connection. Applicant's argument is not persuasive because at column 6, lines 57-67, Crosby teaches that while it is not preferable, it is possible to directly electrically connect the device to a reader for power supply and information gathering. All disclosures of non-preferred embodiments must be considered. *In re Nehrenberg*, 126 PQ 383. *In re Boe*, 148 PQ 507. *In re Mill and Palmer*, 176 PQ 196 (CCPA 1972). *In re Simon*, 174 PQ 114. *In re Lamberti et al.*, 192 PQ 278 (CCPA 1976). Therefore, Crosby only teaches that it is not preferable to directly connect a device to a reader, but does not teach away from this limitation.

7. At pages 10-11, applicant argues that even if the Holmes device is still considered to be a single-use module, applicant disagrees for the reason that each meter of module illustrated in Holmes is arranged with a receptacle for receiving a corresponding electrical connector and multiple receptacles and socket type connectors disclosed by Holmes do not disclose teach or suggest applicant's claimed terminal on a single use device. In response to applicant's argument, while Holmes may teach additional elements on the external of the single-use module, claim 11 recites open transitional claim language "comprising" and therefore does not exclude the presence of additional elements.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641